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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation,	No. MDL 15-02641-PHX DGC
Sherr-Una Booker, an individual, Plaintiff, v. C. R. Bard, Inc., et al. Defendants.	No. CV-16-00474-PHX-DGC **ORDER**

This multidistrict litigation proceeding ("MDL") involves thousands of personal injury cases related to inferior vena cava ("IVC") filters manufactured and marketed by Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively, "Bard"). Plaintiff Sherr-Una Booker, who had a Bard filter implanted ten years ago, brought one of the MDL cases. Plaintiff Booker's case has been selected as one of several bellwether cases and is set for trial in March 2018.

Plaintiffs have filed a motion in limine based on Federal Rules of Evidence 402 and 403 to preclude evidence of (1) the premarket clearance of Bard IVC filters by the Food and Drug Administration ("FDA"), and (2) the lack of FDA enforcement action against Bard. Doc. 9529. The motion is fully briefed, and the parties agree that oral argument is not necessary. The Court will deny the motion.

I. Background.

The IVC is a large vein that returns blood to the heart from the lower body. IVC filters are small metal devices implanted in the IVC to catch blood clots before they reach the heart and lungs. Seven different versions of Bard IVC filters are at issue in this MDL – the Recovery, G2, G2 Express, G2X, Eclipse, Meridian, and Denali.

IVC filters and other medical devices must be approved or cleared for market by the FDA. The FDA may approve a medical device that is shown to be safe and effective through a process known as "premarket approval[.]" 21 U.S.C. § 360e(a). Such approval is not required, however, for most medical devices. Through a less rigorous process known as section "510(k)" review, a manufacturer can obtain "clearance" to market a device by showing that it is substantially equivalent to a device already on the market. 21 U.S.C. § 360c(f)(1)(A). Each Bard IVC filter at issue in this MDL received FDA clearance through 510(k) review.[1]

Plaintiffs allege that Bard filters are more dangerous than other IVC filters because they have a higher risk of tilting, perforating the IVC, or fracturing and migrating to neighboring organs. Plaintiffs further allege that Bard failed to warn physicians and patients about these higher risks. Doc. 303-1. Bard disputes Plaintiffs' allegations, contending that overall complication rates for Bard filters are comparable to those of other IVC filters and that the medical community is aware of IVC filter risks.

Plaintiff Booker was implanted with a G2 filter in June 2007 and suffered injuries from the filter's failure. She asserts various claims against Defendants under Georgia law. Doc. 1, CV-16-00474-PHX-DGC. The following claims remain for trial: design defect, failure to warn, and punitive damages. *See* Doc. 8874 at 22.

II. Federal Rules of Evidence 401, 402, and 403.

The relevance and admissibility of evidence at trial is governed in part by Rules 401, 402, and 403. Evidence is relevant under Rule 401 if it has any tendency to

[1] For further discussion of IVC filters and the FDA regulatory process, see the Court's order regarding preemption. Doc. 8872 at 2-5.

make a material fact more or less probable. Fed. R. Evid. 401(a)-(b). Rule 402 provides that relevant evidence is admissible unless otherwise excluded by the rules, a federal statute, or the Constitution; irrelevant evidence is not admissible. Fed. R. Evid. 402. Under Rule 403, relevant evidence may be excluded if its probative value is substantially outweighed by the danger of "unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence." Fed. R. Evid. 403. Trial courts have discretion to limit or exclude evidence under Rules 402 and 403. *United States v. Scholl*, 166 F.3d 964, 971 (9th Cir. 1999).

III. Discussion.

A. The FDA's Clearance of the G2 Filter Under 501(k) Review.

Plaintiffs argue that Defendants intend to assert an "FDA defense" at trial by implying that the 510(k) clearance process demonstrates filter "safety and effectiveness" and the reasonableness of Bard's conduct. Plaintiffs contend that such evidence is not relevant to any issue in the case and should be excluded under Rule 402. Doc. 9529 at 1-2. The Court does not agree.

Georgia courts have adopted a risk-utility analysis for design defect claims like those asserted by Plaintiff Booker. This analysis incorporates negligence principles and the "concept of 'reasonableness,' i.e., whether the manufacturer acted reasonably in choosing a particular product design[.]" *Banks v. ICI Ams., Inc.*, 450 S.E.2d 671, 673 (Ga. 1994). One of the many factors a jury may consider in its reasonableness determination is the manufacturer's compliance with federal regulations. *Id.* at 675 & n.6. Compliance with the regulations may not render a manufacturer's design choice immune from liability, but it can be a "piece of the evidentiary puzzle." *Doyle v. Volkswagenwerk Aktiengesellschaft*, 481 S.E.2d 518, 521 (Ga. 1997); *see Duran v. Paccar, Inc.*, 549 S.E.2d 755, 762 (Ga. Ct. App. 2001) ("[C]ompliance with federal standards or regulations is probative of Paccar's reasonableness under the risk-utility analysis."). Given these principles of Georgia law, the Court finds that evidence of Bard's compliance with the 510(k) process, while certainly not dispositive, is nonetheless

relevant to the reasonableness of Bard's conduct and whether the company defectively designed the G2 filter.

The evidence is also relevant to Plaintiff's punitive damages claim. Under Georgia law, punitive damages may be awarded only where the defendant's actions showed "willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care which would raise the presumption of conscious indifference to consequences." Ga. Code Ann. § 51-12-5.1(b). Compliance with federal regulations is not sufficient to preclude an award of punitive damages, *see* Doc. 8874 at 18, but it is probative of whether the manufacturer acted with conscious indifference to the dangers posed by its device. *See Stone Man, Inc. v. Green*, 435 S.E.2d 205, 206 (Ga. 1993) (noting that generally "compliance with county, state, and federal regulations is not the type of behavior which supports an award of punitive damages"); *Barger v. Garden Way, Inc.*, 499 S.E.2d 737, 743 (Ga. Ct. App. 1998) (same).

Plaintiffs note, correctly, that the 510(k) process focuses on device equivalence, not device safety. Doc. 9529 at 2 (citing *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 493 (1996)). But this does not render evidence of the 510(k) process irrelevant to the reasonableness of Bard's conduct. The FDA grants 510(k) clearance only where the device "is as safe and effective as a [predicate device] and does not raise different questions of safety and efficacy than the predicate device." Safe Medical Devices Act of 1990, Pub. L. No. 101-629, § 12(a)(1)(A)(ii). The 510(k) process may not speak directly to the applicable standard of care under Georgia law, but it does have probative value in the determination of this action. *See Winebarger v. Boston Sci. Corp.*, No. 3:15CV211-RLV, 2015 WL 5567578, at *7 (W.D.N.C. Sept. 22, 2015) ("The fact that BSC followed the requisite 510(k) protocol – limited as it is – prior to marketing its [medical] device has minimal probative value regarding BSC's efforts to adhere to FDA processes and procedure generally.").

The Court, according to Plaintiffs, already "found that 510(k) clearance is irrelevant to Plaintiffs' state law claims." Doc. 9529 at 2. The Court made no such

finding, and has not previously addressed the question now before it – whether evidence of the 510(k) process is relevant to the claims and defenses in the Booker case.[2]

In their reply brief, Plaintiffs cite a suggested Georgia jury instruction for the proposition that juries are limited to considering only those regulations related to "safety." Doc. 9824 at 2. Plaintiffs note that the cases cited in support of the instruction are the very cases Defendants cite in arguing that a jury may consider federal standards. *Id.*; *see* Doc. 9842-1 at 3 (citing *Banks* and *Doyle*). But in *Banks*, the Georgia Supreme Court made clear that in determining the reasonableness of a manufacturer's conduct, "no finite set of factors can be considered comprehensive or applicable under every factual circumstance, since such matters must necessarily vary according to the unique facts of each case." *Banks*, 450 S.E.2d at 675. And nothing in *Doyle* suggests that only safety regulations may be relevant in design defect cases. *See Doyle*, 481 S.E.2d at 521.

Plaintiffs contend that 510(k) evidence should be excluded under Rule 403 because any probative value it may have is substantially outweighed by the risk of confusion as to whether Bard filters were found by the FDA to be safe and effective. Doc. 9526 at 3-6. Plaintiffs further contend that admission of such evidence would cause the case to devolve into a series of mini-trials regarding the 510(k) process and Bard's compliance with it. *Id.* Plaintiffs note that other courts, including the district court in *Cisson*, have excluded 510(k) evidence under Rule 403. *Id.* at 3-5 & n.2.

In *Cisson*, the court was concerned that allowing 510(k) evidence would create a "substantial risk of misleading the jury to believe that FDA 510(k) clearance might be

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[2] In its ruling on Defendants' preemption motion, the Court noted that "[m]any cases interpret *Riegel* and *Lohr* to mean that PMA approval preempts different or additional requirements imposed by state tort law, while 510(k) clearance does not." Doc. 8872 at 11. The Court then provided a string cite of these cases that included *Cisson v. C. R. Bard, Inc.*, No. 2:11-cv-00195, 2013 WL 5700513, at *12 (S.D. W. Va. Oct. 18, 2013), with this parenthetical quote from *Cisson*: "[T]he 510(k) process does not address product safety and efficacy and therefore is not relevant to Bard's obligations under Georgia state tort law." *Id.* Plaintiffs cite this citation as support for their claim that the Court has resolved the issue in this motion in limine, but that is a real stretch. Not only was the Court not addressing any evidentiary issue in the preemption discussion, it was not even approving the cases included in the string cite. To the contrary, two pages later the Court held that the 510(k) process can in some circumstances preempt state law claims. *Id.* at 13-14.

dispositive of the plaintiffs' state law claims" and would result in a "mini-trial on the 510(k) process and enforcement[.]" *In re C.R. Bard, Inc., Pelvic Repair Sys. Prod. Liab. Litig. (Cisson),* No. 2:10-CV-01224, 2013 WL 3282926, at *2 (S.D.W. Va. June 27, 2013). The Court understands these concerns, but believes they can be adequately addressed without excluding relevant evidence to the detriment of Defendants.

Both sides, through appropriate expert testimony or other admissible evidence, will be permitted to tell the jury about the role of the FDA in its oversight of medical device manufacturers, the regulatory clearance process for devices such as IVC filters, and Bard's participation in the 510(k) process and its compliance (or lack thereof) with that process. *See* Doc. 9433 at 8-9, 16; *Block v. Woo Young Med. Co.,* 937 F. Supp. 2d 1028, 1047 (D. Minn. 2013) (allowing expert witness to testify to "the general nature of the FDA's approval and regulatory process, the FDA's general expectations with respect to testing and marketing of new products, and [the defendant's] actions in that respect"); *Musgrave v. Breg, Inc.*, No. 2:09-CV-01029, 2011 WL 4620767, at *3 (S.D. Ohio Oct. 3, 2011) (denying Rule 403 challenge to 510(k) evidence and noting that the plaintiffs "may argue about what it means, but they cannot keep the jury from hearing the fact that the FDA cleared . . . the [device]"). Defendants will not, however, be permitted to present evidence or argument that the FDA "approved" the G2 filter for market, or that clearance of the device under 510(k) review constitutes a finding by the FDA that the filter is "safe and effective." As relevant FDA regulations explain: "Any representation that creates an impression of official approval of a device because of complying with the [510(k)] premarket notification regulations is misleading[.]" 21 C.F.R. § 807.97. Plaintiffs certainly will be free to present evidence and argument that the 510(k) process is a comparative one that requires only substantial equivalence to a predicate device, that 510(k) regulations are not safety regulations, and – as Plaintiffs claim – that Bard withheld information from the FDA and otherwise failed to fully comply with the 510(k) regulations.

Moreover, any potential confusion can be cured, if necessary, by a limiting instruction regarding the nature of the 510(k) process. *See Winebarger*, 2015 WL 5567578, at *7 (finding 510(k) evidence admissible with "a limiting instruction that 510(k) clearance is not to be considered as evidence that the FDA authorized the [device] as safe and approved its intended use as such," or that the defendant "satisfied any standard of care in designing the . . . device").

It is worth noting that the absence of any evidence regarding the 510(k) process would run the risk of confusing the jury as well. Many of the relevant events in this case occurred in the context of FDA 510(k) review, and much of the evidence is best understood in that context. Attempting to remove any references to the FDA from the trial would risk creating a misleading, incomplete, and confusing picture for the jury. Additionally, the Court is not convinced that all FDA-references could be removed, given that much of the evidence – such as the MAUDE database – comes from the FDA. And if the evidence was half-baked, containing some references to the FDA but not explaining what role the FDA played with respect to the Bard filters, the jury would be left to speculate about the FDA's involvement and conclusions.

The Court is also convinced that efficient management of the evidence and adherence to the Court's time limits will avoid any risk of unnecessary or time-consuming mini-trials. Plaintiffs argue that the parties' regulatory experts likely will take a day each for direct and cross-examination, and that the time limitations set by the Court will prove prohibitive. Doc. 9529 at 6 & n.4. The Court does not agree. The Court is confident that counsel for each side will be able to adequately and efficiently try this case in the time allotted by the Court. *See* Doc. 9415 at 2.

B. The Lack of FDA Enforcement.

Plaintiffs argue that evidence of the lack of FDA enforcement action against Bard is irrelevant, and that it would be misleading and prejudicial for Bard to suggest to the jury that the lack of enforcement signifies product safety. Doc. 9529 at 6-8. Whether evidence that the FDA took no enforcement action against Bard is relevant and otherwise

admissible will depend heavily on the context in which the evidence is offered, including evidence presented by Plaintiffs (such as the FDA warning letter). The Court will make this ruling during trial.

IT IS ORDERED that Plaintiffs' Motion in Limine #1 to exclude evidence of FDA 510(k) clearance and lack of FDA enforcement (Doc. 9529) is **denied**.

Dated this 29th day of January, 2018.

David G. Campbell
United States District Judge